UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/540,108	06/26/2006	Bo Rud Nielsen	P70653US0	1450

136 7590 05/14/2010

JACOBSON HOLMAN PLLC
400 SEVENTH STREET N.W.
SUITE 600
WASHINGTON, DC 20004

EXAMINER	
HEYER, DENNIS	

ART UNIT	PAPER NUMBER
1628	

MAIL DATE	DELIVERY MODE
05/14/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/540,108	NIELSEN ET AL.	
	Examiner	Art Unit	
	DENNIS HEYER	1628	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 February 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/8/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgement is made of Applicant's remarks and amendments filed February 4, 2010. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Status of Claims

Claims 11 – 21 are currently pending

Information Disclosure Statement

The information disclosure statement (IDS) submitted on March 8, 2010 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

New Rejections

Claim Rejections - 35 USC § 112 1st Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11 – 21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The method recited by independent Claims 11 and 20 have been amended to "consisting essentially of" from "comprises". The transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps" and those that do not materially affect the basic and novel characteristics" of the invention (In re Herz, 537 F.2d 549, 551-52 (CCPA 1976)).

If Applicant contends that additional steps or materials in the prior art are excluded by the recitation "consisting essentially of", Applicant has the burden of showing that the introduction of steps or components would materially change the characteristics of Applicant's invention. In re De Lajarte, 337 F.2d 870, 143 USPQ256 (CCPA 1964). See also Ex parte Hoffman, 12 USPQ2d 1061, 1063-64 (Bd.Pat. App. & Inter. 1989) (See MPEP 2111.03 [R-3]). In the instant case, the specification gives no indication as to what materially affects the novel characteristics of the invention or what is a non-material limitation. The specification does not provide a clear indication of whether the sterilization step (carried out by irradiation or autoclaving) of Madsen in

view of Hunter is excluded because such a step would materially affect the novel characteristics of the claimed method to prepare a crosslinked hydrophilic coating on a substrate surface of a medical device as recited in Claim 11. Therefore, absent a clear indication in the specification or claims of what the basic and novel characteristics of the claimed composition actually are, "consisting essentially of' will be construed as equivalent to "comprising." PPG v. Guardian, 156 F.3d 1351, 1354 (Fed. Cir. 1998), see also MPEP 2111.03. For the purpose of examination with respect to the prior art under U.S.C. 102 and 103 the term “consisting essentially of” is construed as being equivalent to the term "comprising". This is a NEW MATTER rejection.

Maintained Rejections

Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 11 – 13 and 15 – 21 *remain* rejected under 35 U.S.C. 103(a) as being unpatentable over Madsen in US 2002/0037943 (published: March 28, 2002) in view of Hunter *et al.* in US 2004/0043052 (filed: May 27, 2003).

This rejection is maintained but has been modified as necessitated by amendment to Claims 11 and 20.

Madsen teaches a method for sterilizing a medical device comprising a hydrophilic coating (Abstract). With respect to claims 11, 17, 19 and 20, Madsen discloses in Examples 2 and 3, a method for the preparation of a cross-linked hydrophilic coating of a hydrophilic polymer on a substrate polymer surface of a medical device (catheter), said method comprising the steps of (i) providing a medical device comprising a substrate polymer having the substrate polymer surface, (ii) providing a polymer solution comprising 1 – 20% by weight of a hydrophilic polymer and 0 – 5% by weight of additive(s), (iii) applying said polymer solution to said substrate polymer surface, (iv) evaporating at least a part of the vehicle from said polymer solution present on said substrate polymer surface, and curing said hydrophilic polymer (Example 1). Amended Claims 11 and 20 now recite the limitation “consisting essentially of” instead of 'comprising'. As noted in the 35 U.S.C. 112, 1st paragraph New Matter rejection above, because neither the instant specification nor the claims indicate what the basic

and novel characteristics of the claimed method actually are, the transitional phrase "consisting essentially of' is construed as equivalent to "comprising" (PPG v. Guardian, 156 F.3d 1351, 1354 (Fed. Cir. 1998), see also MPEP 2111.03).

Madsen teaches a final step, a sterilization step, in which a catheter (a medical device) is permanently wetted (coated) by the wetting liquid and thus ready to use and which is sterilized by irradiation or autoclaving and which will retain the water retention and thus low coefficient of friction when the coatings are stored in water for an extended period of time" (p [0039]). Accordingly, since sterilization by autoclaving is not an irradiation step, Madsen teaches the limitation of instant Claims 11 (step v) and 20 (step b).

Madsen teaches providing a plasticizer (p [0070]), however fails to expressly disclose the polymer solution comprises a vehicle with plasticizing effect on the hydrophilic polymer, said vehicle comprising at least one plasticizer having a solubility in water of at least 6 g/L, a boiling point above 210°C at 760 mmHg, and a Hansen δ_H parameter of less than 20. Hunter *et al.* teach compositions and methods for coating medical implants (Title) and further teaches polymer coatings comprising triethyl citrate as a plasticizer in order to increase the flexibility of the coating (p [0095], [0109]). Since Applicant's example includes the same plasticizer, one of ordinary skill would reasonably construe that triethyl citrate has the same properties as claimed. Therefore, it would have been obvious to one of ordinary skill in the art to modify the type of plasticizer taught by Hunter in the method of Madsen with a plasticizer recognized in the art to increase flexibility in order to attain a coating with the desired properties (desired

flexibility). Further, it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Madsen teaches the polymer solution is applied to the substrate polymer surface in a single application step (dipping) and the vehicle comprises at least one solvent (ethanol) (Examples 2 and 3; instant Claims 12 and 13).

Madsen teaches the substrate polymer is polyurethane and the hydrophilic polymer is polyvinyl pyrrolidone (Examples 2 and 3; instant Claims 15, 16 and 21).

With respect to claim 18 Madsen teaches a medical device comprising a hydrophilic coating of a cross-linked hydrophilic polymer, wherein the coating comprises a plasticizer (p [0070]) but fails to expressly disclose the plasticizer has a solubility in water of at least 6 g/L, a boiling point above 210°C at 760 mmHg, and a Hansen δ_H parameter of less than 20.

Hunter *et al.* teach compositions and methods for coating medical implants (Title) and further teach polymer coatings comprising triethyl citrate as a plasticizer in order to increase the flexibility of the coated device (p [0095], [0109]). Since Applicant's example includes the same plasticizer, one of ordinary skill would reasonably construe that triethyl citrate has the same properties as claimed. Therefore, it would have been obvious to one of ordinary skill in the art to modify the type of plasticizer taught by Hunter in the method of Madsen with a plasticizer recognized in the art to increase flexibility in order to attain a coated device with the desired properties (desired flexibility). Further, it has been held to be within the general skill of a worker in the art to

select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Claim 14 *remains* rejected under 35 U.S.C. 103(a) as being unpatentable over Madsen in US 2002/0037943 (published: March 28, 2002) and Hunter *et al.* in US 2004/0043052 (filed: May 27, 2003), as applied to Claims 11 – 13 and 15 – 21 above, and further in view of Larsen *et al.* in US patent 5,484,565 (published January 16, 1996).

Madsen in combination with Hunter teach the limitations of instant Claims 11 - 13. With respect to claim 14, the modified Madsen discloses that the polymer solution has the ranges claimed hydrophilic polymer and additives but does not teach the recited % weight range of plasticizer.

Larsen teaches methods for making polymer articles such as catheters which are contacted with a solvent and a plasticizer (Abstract). Larsen teaches that when the plasticizer is combined with the swelling agent (solvent) the resulting solution preferably contains 50 – 90 % of the solvent and 1 - 50 % of the plasticizer (column 11, lines 14 – 27). The ranges taught by Larsen are essentially the same as those recited in the instant Claim.

Thus, it would have been *prima facie* obvious to one of ordinary skill in the art, at the time the invention was made, to employ the recited ranges of plasticizer and solvent taught by Larsen in the method of Madsen and Hunter to prepare a coated catheter as such ranges have been taught Larsen to be suited to beneficially modify the flexibility or pliability of a catheter.

Response to Arguments

Applicant's arguments filed October 2, 2009 with respect to the rejection under 35 U.S.C 103(a) of Claims 11 – 21 as being unpatentable over Madsen in US 2002/0037943 in view of Hunter *et al.* in US 2004/0043052 have been fully considered but are found not to be persuasive because the specification does not provide a clear indication of whether the prior art sterilization step (carried out by irradiation or autoclaving) materially affects the novel characteristics of the claimed method. Therefore, because of a lack of a clear indication of what the basic and novel characteristics of the claimed method actually are, the transitional phrase "consisting essentially of' has been construed as "comprising." (MPEP 2111.02, [R-3]). Accordingly, the scope of the claimed invention is, in effect, unchanged and the previously applied 103(a) rejection is maintained.

Conclusion

Claims 11 – 21 are rejected. No claims are allowed.

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DENNIS HEYER whose telephone number is (571)270-7677. The examiner can normally be reached on Monday-Thursday 8AM-5PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, PADMANABHAN SREENIVASAN can be reached at (571)272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DH

/Brandon J Fetterolf/
Primary Examiner, Art Unit 1642